IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

GALDERMA LABORATORIES, L.P. and GALDERMA S.A.,	§	
Plaintiffs,	§	
	§	
v.	§	**CIVIL ACTION NO. 4:10-cv-584**
	§	
PERRIGO CO. and PERRIGO ISRAEL PHARMACEUTICALS LTD.,	§	
	§	
Defendants	§	**Jury Trial Requested**

JOINT STATUS REPORT

Pursuant to the Court's Order To Submit Joint Status Report and Proposed Discovery Plan [doc. #7] dated October 15, 2010, Plaintiffs/Counter-Defendants Galderma Laboratories, L.P. and Galderma S.A. (collectively, "Galderma" or "Plaintiffs") and Defendant Perrigo Co. ("Perrigo Co.") and Defendant/Counter-Plaintiff Perrigo Israel Pharmaceuticals, Ltd. ("Perrigo Israel") (collectively "Defendants" or "Perrigo") file this Joint Status Report of their Rule 26(f)(2) Conference held on November 1, 2010. The following counsel participated by telephone: Michael C. Wilson, Laura A. Russell, and Andrea Swift-Torian for Galderma, and Christine J. Siwik and Alice L. Riechers for Perrigo.

1. **Nature of the case and contentions of the Parties.**

According to USPTO records, Plaintiff Galderma S.A. is the owner of the United States Patent No. 7,316,810 (the "'810 Patent"), entitled "Foaming Composition For Washing and Treating Hair and/or Scalp Based on an Active Principle" and United States Patent No. 7,700,081 (the "'081 Patent), entitled "Foaming Compositions for Hair Care." According to FDA records, Plaintiff Galderma Laboratories, L.P. filed New Drug Application No. 21-644 and,

on February 5, 2004, obtained approval from the FDA to market Clobex® Shampoo (clobetasol propionate shampoo (0.05%)) (hereafter "Clobex® Shampoo") in the United States. The '810 patent and '081 patent are listed in the FDA's approved drug products list (the "Orange Book") in connection with Clobex® Shampoo.

This action arises under the Hatch-Waxman Act, *i.e.*, The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98,417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994) and 35 U.S.C. § 271(d)-(h) (1995)). Perrigo Israel submitted Abbreviated New Drug Application ("ANDA") No. 90-974 to the FDA for clobetasol propionate shampoo, 0.05% (the "Accused Product"), seeking approval to market its ANDA product in the United States. The ANDA contains a "Paragraph IV certification" which contends that the claims of the '810 Patent and '081 Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the Accused Product.

On July 6, 2010, and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), Perrigo Israel sent Galderma a notice letter containing a description of the factual and legal basis for the Paragraph IV certifications that the '810 and '081 patents are invalid, unenforceable, and/or will not be infringed by Perrigo Israel's ANDA product. Galderma, in order to stay FDA approval of Perrigo Israel's ANDA product for up to 30 months, had 45 days from the date of receipt of the notice letter to file a complaint in this case against Perrigo pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

On August 17, 2010, Galderma Laboratories and Galderma S.A. filed this lawsuit alleging a claim against Perrigo for infringement of the '810 Patent and '081 Patent. Galderma contends that the '810 Patent and '081 Patent are valid and enforceable, that Perrigo has infringed the '810 Patent and '081 Patent by submission of the ANDA, and that any manufacture, sale

and/or use of the Accused Product would infringe the '810 Patent and '081 Patent. Galderma seeks injunctive relief, a declaratory judgment and damages if Perrigo commercially manufactures, uses, sells or offers to sell the Accused Product.

On October 14, 2010, Perrigo filed its Answer, Separate Defenses and Counterclaims against Galderma, denying that Plaintiffs are entitled to any relief whatsoever, including a permanent injunction even if the patents-in-suit are found to be valid, enforceable and infringed, and further requesting that Plaintiffs' Complaint be dismissed with prejudice and that Perrigo be awarded its attorney fees and costs incurred in defending this suit under 35 U.S.C. § 285. Perrigo asserted, *inter alia*, defenses that the manufacture, use, or sale of Perrigo Israel's Accused Product has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '810 Patent and/or the '081 Patent; and that the '810 Patent and '081 Patent are invalid under Title 35 of the United States Code. Perrigo also asserted counterclaims seeking declarations that the '810 and '081 patents are not infringed by Perrigo Israel's ANDA product and that the '810 and '081 patents are invalid; seeking dismissal of Plaintiffs' complaint; and declaring that this is an exceptional case under 35 U.S.C. § 285.

2. **Any challenge to jurisdiction or venue.**

Perrigo Co. asserts that this Court lacks subject matter jurisdiction over Galderma's claim for patent infringement against Perrigo Co.

3. **Any matters that require a conference with the Court.**

None at this time.

4. **Likelihood that other parties will be joined, identities of potential parties and an estimate of the time needed for joinder of such parties.**

The Parties currently do not believe that additional parties will be joined in this case.

5. **When disclosures required by FED. R. CIV. P. 26 (a)(1)(A) will be made.**

The Parties agree to serve disclosures on or before November 16, 2010.

6. **A proposed plan and schedule for discovery.**

(a) ***A statement of the subjects on which discovery may be needed***:

All issues raised in the Complaint, Defendants' Answer, and Perrigo Israel's Counterclaims including:

(i) Whether the Accused Product infringes one or more claims of the '810 Patent and/or '081 Patent;

(ii) Whether the claims of the '810 Patent and/or '081 Patent are invalid;

(iii) Whether Perrigo Israel's filing of the ANDA and its defenses or whether Galderma's filing of this lawsuit, make this case exceptional under 35 U.S.C. § 285; and

(iv) Whether, if one or more asserted claims of the patents-in-suit are found to be valid, enforceable and infringed, Plaintiffs are entitled to a permanent injunction.

(b) Completion of factual and expert discovery:

The Parties believe that discovery may be completed as follows:

Completion of fact discovery: December 16, 2011;

Completion of expert discovery: 60 days after rebuttal expert reports.

(c) A statement whether discovery should be conducted in phases or limited to or focused upon particular issues:

Since there have been no sales of Perrigo Israel's proposed generic product, there are no damages at this time. Therefore, there is presently no reason to conduct damages discovery. If it appears that the Court will not be able to try this case before the 30-month stay expires, and if Perrigo Israel launches its generic product before this case is decided and after expiration of the 30-month stay, then the parties may move for damages discovery.

Any discovery on the issue of whether this is an exceptional case should be bifurcated and stayed until the case on the merits is resolved. Bifurcation and staying discovery on exceptional case will eliminate any need for discovery that is unnecessary prior to a decision on the merits of the parties' claims and defenses, will conserve this Court and the parties' resources by avoiding unnecessary discovery disputes, and will avoid severe prejudice to Perrigo.

The Parties believe that having fact discovery close prior to expert discovery would streamline this Hatch-Waxman litigation, as well as help avoid undue costs and possible delays.

7. **What changes should be made in the limitations on discovery imposed under these rules or by local rule, and what other limitations should be imposed:**

a. Limitations on discovery:

The Parties jointly propose a maximum of twenty-five (25) Interrogatories (including subparts) by Plaintiffs to Defendants, and a maximum of twenty-five (25) Interrogatories (including subparts) by Defendants to Plaintiffs. Responses will be due thirty (30) days after service, with additional time for responding as provided by FED. R. CIV. P. 6, unless otherwise agreed to by the parties.

The Parties jointly propose a maximum of ten (10) non-expert depositions by Plaintiffs (collectively), and ten (10) non-expert depositions by Defendants (collectively), and that each deposition be limited to a maximum of seven (7) hours unless extended by agreement of the parties or Order of the Court.

Supplementations under FED. R. CIV. P. 26(e) will be due as provided therein, but not less than forty-five (45) days before trial.

b. Discovery of Electronically Stored Information ("ESI"):

For documents produced to Plaintiffs:

Images will be produced in single-page 300 dpi Group IV tiff images.

(i) An Opticon load file will be provided, or the substantial equivalent; and

(ii) A DAT file with Concordance delimiters that lists BegBates, EndBates, BegAttach, EndAttach, PgCount, PathToText will also be provided; or the substantial equivalent;

(iii) Metadata need not be provided, subject to a party's right to move the Court for metadata in specific instances where such metadata is deemed likely to encompass relevant information.

For documents produced to Defendants:

Images will be produced in single-page 300 dpi (minimum) Group IV tiff images.

(i) A CT Summation DII load file shall be provided; and

(ii) A DAT file with delimiters that lists BegBates, EndBates, BegAttach, EndAttach, PgCount, PathToText will also be provided; or the substantial equivalent;

(iii) Metadata need not be provided, subject to a party's right to move the Court for metadata in specific instances where such metadata is deemed likely to encompass relevant information.

For both parties:

To the extent that a party has responsive electronically-stored documents that cannot conveniently be produced in TIFF format and are more conveniently produced in their native format, and for electronically stored text documents (such as e-mails, word processing files, "Power Point" files, native searchable PDF's and the like), then for such documents:

(i) Native files shall be assigned a document-level Bates number and the file name renamed to the Bates number, or the substantial equivalent;

(ii) Native files shall be organized in a separate folder called "Natives", or the substantial equivalent;

(iii) Insert slip sheet images into the image production indicating the image is a placeholder for a native file, or the substantial equivalent;

(iv) Provide the field "PathToNative" in the DAT file, or the substantial equivalent; and

(iii) Document-level text will be produced in a separate folder called "Text;" or the substantial equivalent.

As an alternative to producing electronically stored documents in native format, a party may produce the documents in PDF format, which shall be searchable if the original file is directly convertible into searchable PDF format, following the same protocol described in the subparagraphs above.

8. **Statement regarding whether any orders should be entered by the Court under FED. R. CIV. P. 26(c) or FED. R. CIV. P. 16 (b)-(c):**

The Parties have submitted with this Joint Status Report a Joint Proposed Initial Scheduling Order attached as Exhibit A, and will submit a proposed Protective Order after meeting and conferring on the terms of such an order.

9. **Jury trial**

A jury trial has been requested in this case on the contingency that the case is not completed before the 30-month stay expires and Perrigo launches its generic product. Otherwise, a jury will not be necessary.

10. **Whether the parties will consent to the referral of this case to a United States magistrate judge who will preside over all pretrial proceedings and trial.**

The Parties do not consent to a trial before a United States Magistrate Judge.

11. **Settlement**

(a) Assessment of the prospects for settlement

The Parties have been engaged in settlement discussions, and continue to engage in settlement negotiations.

(b) Status of settlement negotiations

The Parties continue to engage in settlement negotiations.

(c) Parties' agreement to specific date, place, and time of a formal settlement conference

The Parties continue to engage in ongoing settlement negotiations.

12. **An assessment of whether the dispute would be amendable to mediation.**

The Parties will meet and confer on a mutually agreeable mediator when, and if, they deem mediation to be appropriate and/or productive.

13. ***Dondi* Statement.**

Counsel verifies that they have read the *Dondi* decision, *Dondi Props. Corp. v. Commerce Sav. & Loan Ass'n*, 121 F.R.D. 284 (N.D. Tex. 1988).

14. **Any other matters relevant to the status and disposition of this case.**

None at this time.

Respectfully Submitted,

/s/ *Michael C. Wilson*
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system on this 12th day of November, 2010.

By: /s/ *Michael C. Wilson*
Michael C. Wilson